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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/533,895	09/26/95	TUPALIAN	2026-4205

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18M1/1003

EXAMINER
CAPOTA, A

ART UNIT	PAPER NUMBER
1817	12

DATE MAILED: 10/03/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/553,895

Applicant(s)
Topalin et al.

Examiner
Anthony C. Caputa

Group Art Unit
1817



☒ Responsive to communication(s) filed on Jun 24, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-63 is/are pending in the application.

Of the above, claim(s) 31-55, 57-60, 62, and 63 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-30, 56, and 61 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the search is not undue as exemplified that a search would involve one additional class of art. This is not found persuasive. It is the Examiner's position, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Applicant's argument is sufficient to overcome the election of species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 31-55, 57-60, 62, and 63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention(s), the requirement having been traversed in Paper No. 11.

Information Disclosure Statement

3. The information disclosure statement filed May 19, 1997 (see Paper No. 9) fails to not comply with the provisions of MPEP § 609 because no copy of the references were provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements. See MPEP § 609 ¶ C(1).

The information disclosure statement filed 6/11/97 (Paper No. 10) has been considered

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Specification

4. Sequence rules set forth in 37 C.F.R. § 1.821 require the use of SEQ ID No if the sequence is embedded in the text or in the claims. All sequences must be referred to by use of an identifier such as "SEQ ID NO" as presented in the Sequence Listing even though the sequence itself may be imbedded in the text of the application.

The disclosure and claims of the application mention sequences that are set forth in the Sequence listing but reference is not properly made to the sequence by the use of a sequence identifier in the text.

Claim Rejections - 35 USC § 112

5. Claims 1-30, 56, and 61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides consisting of the amino acid sequence as set forth in SEQID Nos 1, 2, 13, 14, 16 (see page 8, lines 30-35), it does not reasonably provide enablement for the peptides as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (see Burgess et al.). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduce the biological activity of the mitogen (see Lazar et al.). These references demonstrate that a even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the myriad or

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derivatives encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice broadly the claimed invention.

6. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected for being vague and indefinite since it is not clear what constitutes as "requisite activity"?

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. The examiner can be reached on alternate Fridays. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196.

Papers related to this application may be submitted to Art Unit 1817 by facsimile transmission. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The Fax number is (703)-305-3014.

Anthony C. Caputa, Ph.D.
September 30, 1997


ANTHONY C. CAPUTA
PRIMARY EXAMINER
GROUP 1800